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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1

of

2

Complete If Known

Application Number 10/028,989

Filing Date December 28, 2001

First Named Inventor PETTIS et al.

Group Art Unit 3763

Examiner Name Not Yet Assigned

Attorney Docket Number 7767-177409

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
C9N	AA	2,619,962		Rosenthal	12/02/1952	
	AB	3,814,097		Ganderton et al.	05/04/1974	
	AC	3,964,482		Gerviel et al.	06/22/1976	
	AD	4,270,537		Romaine	06/02/1981	
	AE	4,592,753		Panoz	06/03/1986	
	AF	5,003,987		Grinwald	04/02/1991	
	AG	5,098,389		Cappucci	03/24/1992	
	AH	5,156,591		Gross et al.	10/20/1992	
	AI	5,250,023		Lee et al.	10/05/1993	
	AJ	5,279,544		Gross et al.	01/18/1994	
	AK	5,417,662		Hjertman et al.	05/23/1995	
	AL	5,527,288		Gross et al.	06/18/1996	
	AM	5,591,139		Lin et al.	01/07/1997	
	AN	5,801,057		Smart et al.	09/01/1998	
	AO	5,820,622		Gross et al.	10/13/1998	
	AP	5,848,991		Gross et al.	12/15/1998	
	AQ	5,876,582		Frazier	03/02/1999	
	AR	5,879,326		Godshall et al.	03/09/1999	
	AS	5,928,207		Pisano et al.	07/27/1999	
	AT	5,957,895		Sage et al.	09/28/1999	
	AU	5,997,501		Gross et al.	12/07/1999	
	AV	6,099,504		Gross et al.	08/08/2000	
	AW	6,334,856	B1	Allen et al.	01/01/2002	
	AX	6,346,095	B1	Gross et al.	02/12/2002	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₀
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
C9N	AY	CA	2 349 431		Canada	05/25/2000		
	AZ	EP	1 086 718	A1	Europe	03/28/2001		
	BA	EP	1 086 719	A1	Europe	03/28/2001		
	BB	EP	1 088 642	A1	Europe	04/04/2001		
	BC	EP	1 092 444	A1	Europe	04/18/2001		
	BD	WO	96/17648		PCT	06/13/1996		
	BE	WO	96/37155		PCT	11/28/1996		
	BF	WO	96/37256		PCT	11/28/1996		
	BG	WO	99/43350		PCT	09/02/1999		
	BH	WO	99/64580		PCT	12/06/1999		
C9N	BI	WO	00/67647		PCT	11/16/2000		
	BJ	WO	00/74763	A2	PCT	12/14/2000		
	BK	WO	02/11669	A2	PCT	02/14/2002		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

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Application Number	10/028,989
Filing Date	December 28, 2001
First Named Inventor	PETTIS et al.
Group Art Unit	3763
Examiner Name	Not Yet Assigned
Attorney Docket Number	7767-177469

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
OSN.	BL	E. AUTRET et al., Therapie 1991, 46 : 5-8.	
	BM	BRESSOLLE et al., "A Weibull Distribution Model for Intradermal Administration of Cefazidime", Journal of Pharmaceutical Sciences, Vol. 82, No. 11, November 1993, pps. 1175-1178.	
	BN	HENRY et al., "Microfabricated Microneedles: A Novel Approach to Transdermal Drug Delivery", Journal of Pharmaceutical Sciences, Vol. 87, No. 8, August 1998, pps. 922-925.	
	BO	KAUSHIK et al., "Transdermal Protein Delivery Using Microfabricated Microneedles", Oct/Nov 1999 (1 page).	
	BP	BURKOTH et al., "Transdermal and Transmucosal Powered Drug Delivery", Critical Reviews in Therapeutic Drug Carrier Systems, 16 (4), (1999), pps. 331-384.	
OSN.	BQ	MCALLISTER et al., "Three-Dimensional Hollow Microneedle and Microtube Arrays", Conference: Solid-State Sensors and Actuators Transducers-Conference, 1999; 10 th ; Vol. 12, pp 1098-1103.	

Examiner Signature	Catherine S. Williams	Date Considered	1/12/04
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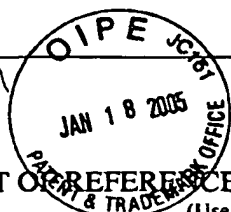
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¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

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LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO.
11219-023-999
(500752-999022;
P4901P4)

APPLICATION NO.
10/028,989

APPLICANT
Ronald J. Pettis, et al.

FILING DATE
December 28, 2001

GROUP
3763

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
(Bn)	A01	4,886,499	12-1989	Cirelli, et al.			
	A02	5,279,552	01-1994	Magnet			
	A03	5,582,591	12-1996	Cheikh			
	A04	5,800,420	09-1998	Gross, et al.			
	A05	5,848,990	12-1998	Cirelli, et al.			
	A06	6,007,821	12-1999	Srivastava, et al.			
	A07	6,056,716	05-2000	D'Antonio, et al.			
	A08	6,319,224	11-2001	Stout, et al.			
	A09	US 2002/0095134	07-2002	Pettis, et al.			
	A10	6,537,242	03-2003	Palmer, Phyllis J.			
(Bn)	A11	US 2003/0073609	04-2003	Pinkerton			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B01	WO 94/23777	10-1994	PCT				
	B02	EP 0 429 842	08-1996	EP				
	B03	WO 97/21457	06-1997	PCT				
	B04	WO 00/09186	02-2000	PCT				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

(Bn)	C01	"Flu vaccine: skin injection method effective in younger people," <i>American Health Line: Research Notes</i> (2004 Nov. 4)
	C02	Agrawal, et al., Pharmacokinetics, Biodistribution, and Stability of Oligodeoxynucleotide Phosphorothioates in Mice, <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 88, pp. 7595-7599, September 1991 Medical Sciences
	C03	Autret, et al., Comparison of Pharmacokinetics and tolerance of Calcitonine administered by Intradermal or Subcutaneous Route, <i>Fundamental Clinical Pharmacology</i> , Vol. 3, No. 2, pp 170-171, 1989
(Bn)	C04	Bader M. Influenza vaccine experience in Seattle. <i>Am. J. Public Health</i> . 1980 May;70(5):545
(Bn)	C05	Belshe et al., "Serum antibody responses after intradermal vaccination against influenza," <i>New England Journal of Medicine</i> 351(22):2286-2294 (2004)
	C06	Benoni, et al., Distribution of Ceftazidime in Ascitic Fluid, <i>Antimicrobial Agents and Chemotherapy</i> , Vol. 25, No. 6, June 1984, pp. 760-763
	C07	Bickers, et al., editors, <i>Clinical Pharmacology of Skin Disease</i> , pp. 57-90, Churchill Livingstone, Inc. 1984
	C08	Bocci, et al., The Lymphatic Route. IV. Pharmacokinetics of Human Recombinant Interferon $\alpha 2$ and Natural Interferon beta Administered Intradermally in Rabbits, <i>International Journal of Pharmaceutics</i> , 32, 1986, pp. 103-110 Elsevier Science Publishers B.V. (Biomedical Division)
(Bn)	C09	Branswell, "Vaccine stretching may be an option for future shortages, pandemics: studies," <i>Canadian Press News Wire</i> (2004 Nov. 3)
	C10	Bronaugh RL, Stewart RF, Congdon ER. Methods for in Vitro Percutaneous Absorption Studies. II. Animal Models for Human Skin. <i>Toxicol. Appl. Pharmacol.</i> 1982 Mar 15;62(3):481-8.
(Bn)	C11	Brooks et al. Intradermal administration of bivalent and monovalent influenza vaccines. <i>Ann. Allergy</i> . 1977 Aug; 39(2):110-2

Qsn.	C12	Brown et al. The immunizing effect of influenza A/New Jersey/76 (Hsw1N1) virus vaccine administered intradermally and intramuscularly to adults. J. Infect. Dis. 1977 Dec;136 Suppl:S466-71
	C13	Callen, Intralesional Corticosteroids, Journal of the American Academy of Dermatology, University of Louisville School of Medicine, pp. 149-151, 1981
	C14	Corbo M, Liu JC, Chien YW. Transdermal Controlled Delivery of Propranolol from a Multilaminate Adhesive Device. Pharm Res. 1989 Sep;6(9):753-8.
	C15	Cossum, et al., Disposition of the C-Labeled Phosphorothioate Oligonucleotide ISIS 2105 after Intravenous Administration to Rats, The Journal of Pharmacology and Experimental Therapeutics, pp. 1181-1190, Vol. 267, No. 3, 1993
	C16	Cossum, et al., Pharmacokinetics of C-Labeled Phosphorothioate Oligonucleotide, ISIS 2105 after Administration to Rats, The Journal of Pharmacology and Experimental Therapeutics, pp. 89-94, Vol. 269, No. 1, 1994
	C17	Crooke, et al., A Pharmacokinetic Evaluation of C-Labeled Afovirsen Sodium in Patients with Genital Warts, Clinical Pharmacology & Therapeutics, pp. 641-646, Vol. 56, No. 6, Part 1, December 1994
Qsn.	C18	Crowe Experimental comparison of intradermal and subcutaneous vaccination with influenza vaccine. Am. J. Med. Technol. 1965 Nov-Dec;31(6):387-96
	C19	Firooz, et al., Benefits and Risks of Intralesional Corticosteroid Injection in the Treatment of Dermatological Diseases, pp. 363-370, Vol. 20, No. 5, Clinical and Experimental Dermatology, Blackwell Science Ltd, September 1995
Qsn.	C20	Fjerstad, "U. Minnesota professor uses alternative flu vaccine technique," FSView & Florida Flambeau via U-Wire (2004 Nov. 15)
Qsn.	C21	Foy et al. Efficacy of intradermally administered A2 Hong Kong vaccine. JAMA. 1970 Jul 6;213(1):130
Qsn.	C22	Glenn et al. Advances in vaccine delivery: transcutaneous immunisation. Exp. Opin. Invest. Drugs 1999, 8(6):797-805
	C23	Goodarzi, et al., Organ Distribution and Stability of Phosphorothioated Oligodeoxyribonucleotides in Mice, Biopharmaceutics & Drug Disposition, pp. 221-227, Vol. 13, No. 3, John Wiley & Sons Ltd., April 1992
Qsn.	C24	Gramzinski et al. Immune response to a hepatitis B DNA vaccine in Aotus monkeys: a comparison of vaccine formulation, route, and method of administration. Mol. Med. 1998 Feb;4(2):109-18
Qsn.	C25	Halperin et al. A comparison of the intradermal and subcutaneous routes of influenza vaccination with A/New Jersey/76 (swine flu) and A/Victoria/75: report of a study and review of the literature. Am. J. Public Health. 1979 Dec;69(12):1247-50
	C26	Haynes, et al., Ultra-long-duration Local Anesthesia Produced by Injection of Lecithin-coated Methoxyflurane Microdroplets, Anesthesiology, Vol. 63, Vol. 5, pp. 490-499, Nov. 1985
Qsn.	C27	Herbert et al. Comparison of responses to influenza A/New Jersey/76-A/Victoria/75 virus vaccine administered intradermally or subcutaneously to adults with chronic respiratory disease. J. Infect. Dis. 1979 Aug;140(2):234-8
	C28	Jakobson, et al., Variations in the Blood Concentration of 1,1,2-Trichloroethane by Percutaneous Absorption and Other Routes of Administration in the Guinea Pig, Vol. 41, No. 5, pp. 497-506, Acta Pharmacologica et Toxicologica, November 1977
	C29	Jarratt, et al., The Effects of Intradermal Steroids on the Pituitary-Adrenal Axis and the Skin, The Journal of Investigative Dermatology, Vol. 62, No. 4, pp. 463-466, 1974
Qsn.	C30	Kenney et al., "Dose sparing with intradermal injection of influenza vaccine," New England Journal of Medicine 351(22):2295-2301 (2004)
	C31	Kirkpatrick, et al., Local Anesthetic Efficacy of Methoxyflurane Microdroplets in Man, Vol. 67, No. 3A, Anesthesiology, September 1987
Qsn.	C32	Knox, "New research shows intradermal rather than intramuscular vaccine injection could stretch flu vaccine supplies," National Public Radio: All Things Considered (2004 Nov. 3)
Qsn.	C33	Kohn, "Flu shot technique yields more doses, studies find; critics say injecting skin rather than muscle is too difficult for common use," The Baltimore Sun: Telegraph 3A (2004 Nov. 4)
	C34	Leroy, et al., Pharmacokinetics of Cefazidime in Normal and Uremic Subjects, Antimicrobial Agents and Chemotherapy, Vol. 25, No. 5, pp. 638-642, May 1984
Qsn.	C35	Majeski, "Alternative flu shot less effective in elderly; doctors proposed method to stretch vaccine supply," Saint Paul Pioneer Press(Minnesota): Main 17A (2004 Nov. 4)
Qsn.	C36	Majeski, "Technique could stretch vaccine; changing the way shots are given means the current supply of flu vaccine could immunize 10 times as many people, two Minnesota physicians say" Saint Paul Pioneer Press(Minnesota): Main 1A (2004 Oct. 27)
Qsn.	C37	Marian et al. 2001, Acta Biologica Hungarica, 52(1): 35-45
	C38	McAllister et al., Solid and Hollow Microneedles for Transdermal Protein Delivery. Proceed. Intl. Symp. Control. Rel. Bioact. Mater., 26 (Revised July 1999) Controlled Release Society, Inc. pp. 192-193
Qsn.	C39	McElroy et al. Response to intradermal vaccination with A2, Hong Kong variant, influenza vaccine. N. Engl. J. Med. 1969 Nov 6;281(19):1076
	C40	McGugan, et al., Adrenal Suppression from Intradermal Triamcinolone. The Journal of Investigative Dermatology, Vol. 40, pp. 271-272, Baltimore, MD., 1963
	C41	Merriam-Webster's Collegiate Dictionary, 10 th Edition, 1998, Merriam-Webster, Inc., Springfield, MA, p. 306
Qsn.	C42	Montagne et al., "Intradermal influenza vaccination - can less be more?" New England Journal of Medicine 351(22):2330-2332 (2004)
Qsn.	C43	Niculescu et al. Efficacy of an adsorbed trivalent split influenza vaccine administered by intradermal route. Arch. Roum. Path. Exp. Microbiol. 1981, 40(1):67-70

C44	Payler DK. Intradermal influenza vaccine using Portojet 1976. Br. Med. J. 1977 Oct 29;2(6095):1152
C45	Payler et al. Letter: Intradermal influenza vaccination. Br. Med. J. 1974 Jun 29;2(921):727
C46	Rindfleisch, "La Crosse finding could curtail flu vaccine shortages," <i>Wisconsin State Journal</i> D9 (2004 Nov. 14)
C47	Scott, et al., Toxicity of Interferon, Vol. 282, pp. 1345-1348, British Medical Journal, April 25, 1981
C48	Shute, "Second thoughts on the flu vaccine," <i>U.S. News & World Report</i> 137(17):80
C49	Smith, "Low-dose vaccine helps block flu, study says younger adults seen benefiting," <i>The Boston Globe: National/Foreign A2</i> (2004 Nov. 4)
C50	Supersaxo, et al., Recombinant Human Interferon Alpha-2a: Delivery to Lymphoid Tissue by Selected Modes of Application, <i>Pharmaceutical Research</i> , Vol. 5, No. 8, pp. 472-476, August 1998
C51	Sutherest, Treatment of Pruritus Vulvae by Multiple Intradermal Injections of Alcohol. A Double-Blind Study, Vol. 86, pp. 371-373, <i>British Journal of Obstetrics and Gynecology</i> , May 1979
C52	Sveinsson, 1939, Investigation on the Influence of Insulin and Adrenalin in Rabbits with Alimentary Fatty Liver and Muscles and on the Content of Fat and Sugar in Blood, Oslo, Norway (pp. 66-86)
C53	Tauraso et al. Effect of dosage and route of inoculation upon antigenicity of inactivated influenza virus vaccine (Hong Kong strain) in man. <i>Bull. World Health Organ.</i> 1969;41(3):507-16
C54	The American Heritage College Dictionary, 2000, 3 rd Edition; Houghton Mifflin Company, Boston, New York, p. 368
C55	The Merck Manual of Diagnosis and Therapy, 1999, 17 th Edition, Beers & Berkow, ed., Merck Research Laboratories, Division of Merck & Co., Inc., Whitehouse Station, NJ, pp. 2559-2567
C56	Ward, et al., Puritus Vulvae: Treatment by Multiple Intradermal Alcohol Injections, Vol. 93, No. 2, pp. 201-204, <i>British Journal of Dermatology</i> , August 1975
C57	Wu, et al., Pharmacokinetics of Methoxyflurane after its Intra-Dermal Injection as Lecithin-Coated Microdroplets, Vol. 9, pp. 1-12, <i>Journal of Controlled Release</i> , July 1989
C58	Zaynoun, et al., The Effect of Intracutaneous Glucocorticoids on Plasma Cortisol Levels, Vol. 88, No. 2, pp. 151-156, <i>British Journal of Dermatology</i> , February 1973

EXAMINER

Catherine S. Williams

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